



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Development and Commercialization of Therapies To Treat IGF-1 Deficiency and Achondroplasia

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute and the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, of the National Institutes of Health, Department of Health and Human Services, are contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the Supplementary Information section of this notice to PreciThera, Inc, located in Montreal, Canada.

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute's Technology Transfer Center on or before [INSERT DATE 15 DAYS FROM DATE OF PUBLICATION OF NOTICE IN THE FEDERAL REGISTER] will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated an Exclusive Patent License should be directed to: Martha T. Lubet, Ph.D., Licensing and Patenting Manager, NCI Technology Transfer Center, Telephone: (240)-276-5530 or E-mail: lubetm@mail.nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

(United States Provisional) Patent Application No. 61/927904, filed January 15, 2014 and entitled: "Cartilage Targeting Agents and Their Use" [HHS Reference No. E-003-2014/0-US-01];

(PCT) Patent Application PCT/US2015/011433, filed January 14, 2015 and entitled “Cartilage Targeting Agents and Their Use” [HHS Reference No. E-003-2014/0-PCT-02]; (and U.S. and foreign patent applications claiming priority to the aforementioned applications).

The patent rights in these inventions have been assigned and/or exclusively licensed to the government of the United States of America.

The prospective exclusive license territory may be worldwide, and the field of use may be limited to the following:

- A)** a fusion protein comprising one of the anti-matrilin 3 binding agents and insulin-like growth factor 1 (IGF-1) for the treatment of short stature of humans with primary IGF-1 deficiency and
- B)** a fusion protein comprising one of anti-matrilin 3 binding agents and C-type natriuretic protein for the treatment of humans with achondroplasia.

This technology discloses antigen binding antibody fragments that bind to matrilin-3. These agents were selected from a yeast display antibody library for the ability to bind to human or mouse matrilin-3. Matrilin-3 is strongly expressed in the epiphyseal growth plate of bones. In some embodiments, the antibody fragments are linked to an effector molecule (e.g. growth hormone, IGF-1, or C-type natriuretic protein). Methods of using the anti-Matrilin-3 binding agents to treat skeletal dysplasia, short stature and osteoarthritis are also disclosed.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR Part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Cancer Institute and the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development receive written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information in these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 USC 552.

Dated: July 28, 2020.

Richard U. Rodriguez,
Associate Director,
Technology Transfer Center,
National Cancer Institute.

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